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## 510(K) NOTIFICATION

Sigma Diagnostics  
545 South Ewing Avenue  
St. Louis, MO 63103

CX®3 Glucose Reagent  
Procedure Number G4903  
August 31, 1996

### SUMMARY OF SAFETY AND EFFECTIVENESS

The diagnosis of disorders associated with abnormal carbohydrate metabolisms depends in part on the measurement of glucose. The most significant of these diseases is diabetes mellitus, which is characterized by abnormally high concentrations of glucose in physiological fluids. Increased glucose concentration also occurs during hyperactivity of endocrine glands such as the thyroid and the adrenal. Hypoglycemia is a condition characterized by low glucose levels that can result from a variety of conditions such as insulin overdose, liver diseases, and hypopituitarism.<sup>1</sup> Glucose determinations, therefore, are useful for detection and management of diabetes mellitus, and for investigation of hypoglycemic conditions.

Quantitative measurement of glucose by means of a modified polarographic oxygen sensor for recording oxygen consumption was introduced in 1969 by A. Kadish, et al.<sup>2</sup> The Sigma Diagnostics Glucose Reagent is formulated to use this methodology on the SYNCHRON CX®3 System.

The safety and effectiveness of Sigma Diagnostics Glucose Reagent, Procedure Number G4903, are demonstrated by its substantial equivalency to Beckman Glucose Reagent Kit, Part No. 443355. Both glucose reagents are used to measure glucose concentrations in serum, plasma, urine, or CSF on the SYNCHRON CX®3 System, and the reaction principles for both reagents are identical. In comparison studies, a correlation coefficient of 0.997 and a regression equation of  $y = 1.01x - 1.73$  was obtained with serum samples; a correlation coefficient of 0.976 and a regression equation of  $y = 0.97x - 2.68$  was obtained with urine samples; and a correlation coefficient of 0.981 and a regression equation of  $y = 1.02x - 2.95$  was obtained with CSF samples. With-in run precision and total precision demonstrated % CV's of less than 2.0 % on serum samples; less than 3.8 % on urine samples; and less than 2.3 % on CSF samples. The Sigma Diagnostics Glucose Reagent has been determined to be linear to 900 mg/dL using the ORDAC function on the SYNCHRON CX®3 System.

### REFERENCES:

1. Searcy RL: Diagnostic Biochemistry. McGraw Hill, New York, 1969, pp 460-464
2. Kadish A, et al: J Clin Chem 14(2):16, 1968